

Dated: June 8, 2010.
Mark J. Musaus,
Acting Regional Director.
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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-318R]

Controlled Substances: Proposed Revised Aggregate Production Quotas for 2010

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed revised 2010 aggregate production quotas.

SUMMARY: This notice proposes revised 2010 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA).

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before July 23, 2010.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-318R" on all written and electronic correspondence. Written comments should be sent to the DEA Headquarters, *Attention:* DEA Federal Register Representative/ODL, 8701 Morrisette Drive, Springfield, VA 22152. Comments may be directly sent to DEA electronically by sending an

electronic message to *dea.diversion.policy@usdoj.gov*. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. However, persons wishing to request a hearing should note that such requests must be written and manually signed; requests for a hearing will not be accepted via electronic means. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, *Telephone:* (202) 307-7183.

SUPPLEMENTARY INFORMATION: Section 306 of the CSA (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100. The Administrator in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104.

On May 21, 2009, a notice of proposed 2010 aggregate production quotas for certain controlled substances in schedules I and II was published in the **Federal Register** (74 FR 23881). This

notice stipulated that the DEA would adjust the quotas in 2010 as provided for in 21 CFR part 1303. The 2010 established aggregate production quotas were published in the **Federal Register** (74 FR 54080) on October 21, 2010.

The proposed revised 2010 aggregate production quotas represent those quantities of controlled substances in schedules I and II that may be produced in the United States in 2010 to provide adequate supplies of each substance for: The estimated medical, scientific, research and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes.

The proposed revisions are based on a review of 2009 year-end inventories, 2009 disposition data submitted by quota applicants, estimates of the medical needs of the United States, product development, and other information available to the DEA.

Therefore, under the authority vested in the Attorney General by Section 306 of the CSA (21 U.S.C. 826), and delegated to the Administrator of the DEA by 28 CFR 0.100, and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator hereby proposes the following revised 2010 aggregate production quotas for the following controlled substances, expressed in grams of anhydrous acid or base:

Basic class	Previously established initial 2010 quotas	Proposed revised 2010 quotas
Schedule I		
2,5-Dimethoxyamphetamine	2 g	2 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2 g	2 g
3-Methylfentanyl	2 g	2 g
3-Methylthiofentanyl	2 g	2 g
3,4-Methylenedioxyamphetamine (MDA)	25 g	20 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	10 g	10 g
3,4-Methylenedioxymethamphetamine (MDMA)	20 g	20 g
3,4,5-Trimethoxyamphetamine	2 g	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2 g	2 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	2 g	2 g
4-Methoxyamphetamine	77 g	77 g
4-Methylaminorex	2 g	2 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2 g	2 g
5-Methoxy-3,4-methylenedioxyamphetamine	2 g	2 g
5-Methoxy-N,N-diisopropyltryptamine	5 g	0 g
Acetyl-alpha-methylfentanyl	2 g	2 g
Acetyldihydrocodeine	2 g	2 g
Acetylmethadol	2 g	2 g
Allylprodine	2 g	2 g
Alphacetylmethadol	2 g	2 g
Alpha-ethyltryptamine	2 g	2 g
Alphameprodine	2 g	2 g
Alphamethadol	2 g	2 g
Alpha-methylfentanyl	2 g	2 g
Alpha-methylthiofentanyl	2 g	2 g

Basic class	Previously established initial 2010 quotas	Proposed revised 2010 quotas
Alpha-methyltryptamine (AMT)	2 g	2 g
Aminorex	2 g	2 g
Benzylmorphine	2 g	2 g
Betacetylmethadol	2 g	2 g
Beta-hydroxy-3-methylfentanyl	2 g	2 g
Beta-hydroxyfentanyl	2 g	2 g
Betameprodine	2 g	2 g
Betamethadol	2 g	2 g
Betaprodine	2 g	2 g
Bufotenine	3 g	3 g
Cathinone	3 g	3 g
Codeine-N-oxide	602 g	602 g
Diethyltryptamine	2 g	2 g
Difenoxin	3,000 g	3,000 g
Dihydromorphine	3,300,000 g	3,500,000 g
Dimethyltryptamine	3 g	3 g
Gamma-hydroxybutyric acid	24,200,000 g	52,156,000 g
Heroin	20 g	20 g
Hydromorphenol	2 g	2 g
Hydroxypethidine	2 g	2 g
Ibogaine	1 g	1 g
Lysergic acid diethylamide (LSD)	15 g	15 g
Marihuana	4,500,000 g	11,000 g
Mescaline	7 g	5 g
Methaqualone	7 g	7 g
Methcathinone	4 g	4 g
Methyldihydromorphine	2 g	2 g
Morphine-N-oxide	605 g	605 g
N-Benzylpiperazine	2 g	2 g
N,N-Dimethylamphetamine	7 g	2 g
N-Ethylamphetamine	2 g	2 g
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g	2 g
Noracetylmethadol	2 g	2 g
Norlevorphanol	52 g	52 g
Normethadone	2 g	2 g
Normorphine	16 g	16 g
Para-fluorofentanyl	2 g	2 g
Phenomorphan	2 g	2 g
Pholcodine	2 g	2 g
Psilocybin	7 g	2 g
Psilocyn	7 g	2 g
Tetrahydrocannabinols	312,500 g	216,000 g
Thiofentanyl	2 g	2 g
Trimeperidine	2 g	2 g

Schedule II

1-Phenylcyclohexylamine	2 g	2 g
1-Piperidinocyclohexanecarbonitrile	2 g	0 g
Alfentanil	8,000 g	6,300 g
Alphaprodine	2 g	2 g
Amobarbital	3 g	3 g
Amphetamine (for sale)	17,000,000 g	17,000,000 g
Amphetamine (for conversion)	6,500,000 g	6,500,000 g
Cocaine	247,000 g	247,000 g
Codeine (for sale)	39,605,000 g	39,605,000 g
Codeine (for conversion)	65,000,000 g	65,000,000 g
Dextropropoxyphene	106,000,000 g	92,000,000 g
Dihydrocodeine	1,200,000 g	800,000 g
Diphenoxylate	947,000 g	627,000 g
Ecgonine	83,000 g	83,000 g
Ethylmorphine	2 g	2 g
Fentanyl	1,428,000 g	1,428,000 g
Glutethimide	2 g	2 g
Hydrocodone (for sale)	55,000,000 g	55,000,000 g
Hydromorphone	3,300,000 g	3,455,000 g
Isomethadone	11 g	11 g
Levo-alphaacetylmethadol (LAAM)	3 g	3 g
Levomethorphan	5 g	5 g
Levorphanol	10,000 g	10,000 g
Lisdexamfetamine	9,000,000 g	9,000,000 g
Meperidine	8,600,000 g	6,600,000 g

Basic class	Previously established initial 2010 quotas	Proposed revised 2010 quotas
Meperidine Intermediate-A	3 g	3 g
Meperidine Intermediate-B	7 g	7 g
Meperidine Intermediate-C	3 g	3 g
Metazocine	1 g	1 g
Methadone (for sale)	25,000,000 g	20,000,000 g
Methadone Intermediate	26,000,000 g	26,000,000 g
Methamphetamine	3,130,000 g	3,130,000 g
[750,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,331,000 grams for methamphetamine mostly for conversion to a schedule III product; and 49,000 grams for methamphetamine (for sale)]		
Methylphenidate	50,000,000 g	50,000,000 g
Morphine (for sale)	35,000,000 g	35,000,000 g
Morphine (for conversion)	100,000,000 g	83,000,000 g
Nabilone	9,002 g	9,002 g
Noroxymorphone (for sale)	10,000 g	5,000 g
Noroxymorphone (for conversion)	9,000,000 g	9,000,000 g
Opium (powder)	230,000 g	230,000 g
Opium (tincture)	1,050,000 g	1,050,000 g
Oripavine	15,000,000 g	15,000,000 g
Oxycodone (for sale)	88,000,000 g	88,000,000 g
Oxycodone (for conversion)	4,000,000 g	4,000,000 g
Oxymorphone	2,570,000 g	2,570,000 g
Oxymorphone (for conversion)	12,000,000 g	12,000,000 g
Pentobarbital	28,000,000 g	28,000,000 g
Phenazocine	1 g	1 g
Phencyclidine	20 g	14 g
Phenmetrazine	2 g	2 g
Phenylacetone	12,500,001 g	12,500,001 g
Racemethorphan	2 g	2 g
Remifentanyl	500 g	2,500 g
Secobarbital	67,000 g	67,000 g
Sufentanyl	10,300 g	7,000 g
Thebaine	126,000,000 g	126,000,000 g

The Deputy Administrator further proposes that aggregate production quotas for all other schedules I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero.

All interested persons are invited to submit their comments in writing or electronically regarding this proposal following the procedures in the **ADDRESSES** section of this document. A person may object to or comment on the proposal relating to any of the above-mentioned substances without filing comments or objections regarding the others. If a person believes that one or more of these issues warrant a hearing, the individual should so state and summarize the reasons for this belief. Persons wishing to request a hearing should note that such requests must be written and manually signed; requests for a hearing will not be accepted via electronic means. In the event that comments or objections to this proposal raise one or more issues which the Deputy Administrator finds warrant a hearing, the Deputy Administrator shall order a public hearing by notice in the **Federal Register**, summarizing the

issues to be heard and setting the time for the hearing as per 21 CFR 1303.13(c).

Regulatory Certifications
Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this action will not have a significant economic impact upon small entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601–612. The establishment of aggregate production quotas for schedules I and II controlled substances is mandated by law and by international treaty obligations. The quotas are necessary to provide for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and the establishment and maintenance of reserve stocks. While aggregate production quotas are of primary importance to large manufacturers, their impact upon small entities is neither negative nor beneficial. Accordingly, the Deputy Administrator has determined that this action does not require a regulatory flexibility analysis.

Executive Order 12866

The Office of Management and Budget has determined that notices of aggregate production quotas are not subject to centralized review under Executive Order 12866.

Executive Order 13132

This action does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this action does not have federalism implications warranting the application of Executive Order 13132.

Executive Order 12988

This action meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Unfunded Mandates Reform Act of 1995

This action will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$126,000,000 or more (adjusted for inflation) in any one year,

and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This action is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This action will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Dated: June 17, 2010.

Michele M. Leonhart,
Deputy Administrator.

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DEPARTMENT OF LABOR

Employee Benefits Security Administration

Proposed Extension of Information Collection Request Submitted for Public Comment; Prohibited Transaction Class Exemption 91-55—Transactions Between Individual Retirement Accounts and Authorized Purchasers of American Eagle Coins

AGENCY: Employee Benefits Security Administration, Department of Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (the Department), in accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the reporting burden on the public and helps the public understand the Department's information collection requirements and provide the requested data in the desired format. Currently, the Employee Benefits Security Administration is soliciting comments on the proposed extension of the information collection provisions of Prohibited Transaction Class Exemption 91-55. A copy of the information collection request (ICR) may be obtained by contacting the office listed in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office shown in the Addresses section on or before August 23, 2010.

ADDRESSES: G. Christopher Cosby, Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Washington, DC 20210, (202) 693-8410, FAX (202) 693-4745 (these are not toll-free numbers).

SUPPLEMENTARY INFORMATION:

I. Background

Prohibited Transaction Exemption 91-55 permits purchases and sales by certain "individual retirement accounts," as defined in Internal Revenue Code section 408 (IRAs) of American Eagle bullion coins ("Coins") in principal transactions from or to broker-dealers in Coins that are "authorized purchasers" of Coins in bulk quantities from the United States Mint and which are also "disqualified persons," within the meaning of Code section 4975(e)(2), with respect to IRAs. The exemption also describes the circumstances under which an interest-free extension of credit in connection with such sales and purchases is permitted. In the absence of an exemption, such purchases and sales and extensions of credit would be impermissible under the Employee Retirement Income Security Act of 1974 (ERISA).

Among other conditions, the exemption requires certain information related to covered transactions in Coins must be disclosed by the authorized purchaser to persons who direct the transaction for the IRA. Currently, it is standard industry practice that most of this information is provided to persons directing investments in an IRA when transactions in Coins occur. The exemption also requires that the disqualified person maintain for a period of at least six years such records as are necessary to allow accredited persons, as defined in the exemption, to determine whether the conditions of the transaction have been met. Finally, an authorized purchaser must provide a confirmation statement with respect to each covered transaction to the person who directs the transaction for the IRA. The requirements constitute information collections within the meaning of the PRA, for which the Department has obtained approval from the Office of Management and Budget (OMB) under OMB Control No. 1210-0079. The OMB approval is currently scheduled to expire on August 31, 2010.

The recordkeeping requirement facilitates the Department's ability to

make findings under section 408 of ERISA and section 4975(c) of the Code. The confirmation and disclosure requirements protect a participant or beneficiary who invests in IRAs and transacts in Coins with authorized purchasers by providing the investor or the person directing his or her investments with timely information about the market in Coins and about the individual's account in particular.

II. Current Actions

This notice requests public comment pertaining to the Department's request for extension of OMB approval of the information collection contained in PTE 91-55. After considering comments received in response to this notice, the Department intends to submit an ICR to OMB for continuing approval. No change to the existing ICR is proposed or made at this time. An agency may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a valid OMB control number. A summary of the ICR and the current burden estimates follows:

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Prohibited Transaction Class Exemption 91-55.

Type of Review: Extension of a currently approved collection of information.

OMB Number: 1210-0079.

Affected Public: Individuals or households; Business or other for-profit; Not-for-profit institutions.

Respondents: 3.

Responses: 663,431.

Frequency: On occasion.

Estimated Total Burden Hours: 11,063.

Estimated Total Burden Cost: \$152,589.

III. Focus of Comments

The Department of Labor (Department) is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the